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10/725,374	12/03/2003	Ralph Schneider	HO-US035151	3133

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EXAMINER
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AHMED, AAMER S

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/725,374

Applicant(s)

SCHNEIDER ET AL.

Examiner

Aamer S. Ahmed

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12/3/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/5/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Specification***

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
3. The disclosure is objected to because of the following informalities: incorrect prior art patent number 6,387,076 referred to in specification, should appear as 6,387,075.
4. Appropriate correction is required.
5. The disclosure is objected to because of the following informalities: catheter shaft is referred to as 7, should be referred to as 2, (Paragraph 0030).
6. Appropriate correction is required.

### ***Drawings***

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the spiral spring must be shown or the feature canceled from the claims. No new matter should be entered.
8. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### ***Claim Objections***

9. Claim 7 is objected to because of the following informalities: the claim recites "the seal" in reference to claim 3, however claim 3 contains no such limitation. Claim 6 does recite a seal. Claim 7 will be treated to be dependent on Claim 6. If this is not intended, Claim 7 should be amended. Appropriate correction is required.

10. Claim 8 is objected to because of the following informalities: the claim recites "the seal" in reference to claim 4, however claim 4 contains no such limitation. Claim 5 does recite a seal. Claim 8 will be treated to be dependent on Claim 5. If this is not intended, Claim 8 should be amended. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  12. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
13. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
14. Claim 1 recites the limitation "a distal end preferably secured thereto a balloon..."
15. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
16. Claim 7 recites the limitation ""preferably by an adhesive . . ."
17. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
18. Claim 8 recites the limitation ""preferably by an adhesive . . ."
19. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

***Claim Rejections - 35 USC § 102***

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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21. A person shall be entitled to a patent unless –

22. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ressemann ('291).

24. As to claim 1 Ressemann ('291) describes a catheter shaft including a proximal end and a distal end having secured thereto a balloon, and a luer fitting arranged at the proximal end of the catheter shaft, and the proximal end of the catheter shaft being provided with a bending section, (See Figure 1).

25. Thus Ressemann ('291) reasonably appears to teach and disclose every element of claim 1 and therefore anticipates this claim.

26. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Ressemann ('291).

27. As to claim 11 Ressemann ('291) describes a catheter shaft including a proximal end and a distal end having secured thereto a balloon, and a luer fitting arranged at the proximal end of the catheter shaft, and the proximal end of the catheter shaft being provided with a bending section, (See Figure 1). Furthermore, Ressemann ('291) discloses a transition member, 60 of the fitting, consisting of plastic, which forms the bending section (See Figure 2 and Column 9 lines 59-64).

***Claim Rejections - 35 USC § 103***

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28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

29. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

31. Determining the scope and contents of the prior art.
32. Ascertaining the differences between the prior art and the claims at issue.
33. Resolving the level of ordinary skill in the pertinent art.
34. Considering objective evidence present in the application indicating obviousness or nonobviousness.

35. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) in view by Meyer ('978).

36. Ressemann ('291) discloses a catheter shaft including a proximal end and distal end having secured thereto a balloon, a luer fitting at the proximal end of the catheter shaft and the proximal end of the catheter shaft having a bending section (See Figure 1). Ressemann ('291) fails to disclose that the bending section has flexibility greater than that of the section of the catheter shaft joining the proximal end.

37. Meyer ('978) describes a catheter wherein the bending section, 11 has flexibility greater than that of the section of the catheter shaft joining the proximal end, (See Figure 1).

38. It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the Ressemann ('291) proximal bending section of

the catheter shaft by making it more flexible than that of the catheter shaft joining the proximal end in order to create a less kink prone catheter, of the type disclosed by Meyer ('978).

39. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) in view of Tittel ('482).

40. Ressemann ('291) discloses a catheter shaft including a proximal end and distal end having secured thereto a balloon, a luer fitting at the proximal end of the catheter shaft and the proximal end of the catheter shaft having a bending section (See Figure 1). Ressemann ('291) fails to disclose the bending section have a spiral cut into the proximal end of the catheter shaft.

41. Tittel ('482) describes a flexible tube having a spiral cut into the tubing wall (See Figure 1).

42. Accordingly, It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the Ressemann ('291) proximal bending section of the catheter shaft by adding spiral cuts to the section as taught by Tittel

43. ('482) in order to obtain a more flexible proximal catheter shaft section of the type disclosed by Ressemann ('291).

44. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) in view of Schwartz ('520).

45. Ressemann ('291) discloses a catheter shaft including a proximal end and distal end having secured thereto a balloon, a luer fitting at the proximal end of the catheter shaft and the proximal end of the catheter shaft having a bending section (See Figure



1). Ressemann ('291) fails to disclose the presence of a plurality of offset cuts on the bending section.

46. Schwartz ('520) describes a bending section formed by a plurality of offset cuts (See Figure 17).

47. It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the Ressemann ('291) proximal bending section of the catheter shaft by adding offset cuts to the section as taught by Schwartz in order to obtain a more flexible proximal catheter shaft section of the type disclosed by Ressemann ('291).

48. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) in view of Schwartz ('520).

49. Ressemann ('291) discloses a catheter shaft including a proximal end and distal end having secured thereto a balloon, a luer fitting at the proximal end of the catheter shaft and the proximal end of the catheter shaft having a bending section (See Figure

1). Ressemann ('291) fails to disclose the presence of a plurality of offset cuts on the bending section and fails to disclose a seal.

50. Schwartz ('520) describes a bending section formed by a plurality of offset cuts (See Figure 17).

51. Furthermore, Schwartz ('520) proceeds to describe a biocompatible encasing or seal (104) over the cut section (See Figure 20).

52. It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the Ressemann ('291) proximal bending section of

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the catheter shaft by adding offset cuts to the section as taught by Schwartz in order to obtain a more flexible proximal catheter shaft section of the type disclosed by Schwartz ('520) and further to provide a seal over the offset cut section in order to prevent fluid loss from the cut section, also of the type disclosed by Schwartz ('520).

53. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) and Tittel ('482) as applied to claim 3 above and further in view of Larson ('338).

54. Ressemann ('291) discloses a catheter shaft including a proximal end and distal end having secured thereto a balloon, a luer fitting at the proximal end of the catheter shaft and the proximal end of the catheter shaft having a bending section (See Figure 1). Ressemann ('291) fails to disclose the presence of spiral cuts on the bending section of the proximal end of the catheter shaft and fails to disclose the presence of a seal.

55. Tittel ('482) discloses flexible tubing having spiral cuts, but fails to disclose the presence of a seal.

56. Larson ('338) describes a bending section having a spiral cut transition member over the proximal end of the catheter shaft. (See Figure 5) and further describes the presence of a seal or outer tubing over the bending section, 200( See Figure 5).

57. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the Ressemann ('291) proximal bending section of the catheter shaft by adding spiral cuts as described by Tittel ('482) and a seal over to the section as taught by Larson ('338) in order to obtain a more flexible

proximal catheter shaft section of the type disclosed by Ressemann ('291) and Tittel ('482) and further to prevent fluid loss of the type disclose by Larson ('338).

58. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) and Tittel ('482) as applied to clam 3 above and further in view of Larson ('338).

59. Ressemann ('291) discloses a catheter shaft including a proximal end and distal end having secured thereto a balloon, a luer fitting at the proximal end of the catheter shaft and the proximal end of the catheter shaft having a bending section (See Figure 1). Moreover Ressemann ('291) discloses the use of an adhesive to join sections of the catheter shaft,

60. "The proximal end 32 of the distal shaft 23 extends over the distal end  
61. 30 of the main shaft section 22 and is attached thereto by a suitable bond such  
62. as a cyanoacrylate adhesive" (See Column 6 lines 28-30).

63. Ressemann ('291) fails to disclose the presence of spiral cuts on the bending section of the proximal end of the catheter shaft and fails to disclose the presence of a seal.

64. Tittel ('482) discloses flexible tubing having spiral cuts, but fails to disclose the presence of a seal.

65. Larson ('338 describes the presence of a seal or outer tubing fastened to the proximal end of the catheter shaft, 200 (See Figure 5).

66. It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the Ressemann ('291) proximal bending section of the catheter shaft, by adding spiral cuts as taught by Tittel ('482) and affixing a seal over

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the section as taught by Larson ('338) in order to obtain a more flexible and fluid sealed proximal catheter shaft section of the type disclosed by Larson ('338).

67. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) and Schwartz ('520) as applied to claim 3 above and further in view of Ressemann ('291).

68. Ressemann ('291) discloses a catheter shaft including a proximal end and distal end having secured thereto a balloon, a luer fitting at the proximal end of the catheter shaft and the proximal end of the catheter shaft having a bending section (See Figure 1).

69. Moreover Ressemann ('291) discloses the use of an adhesive to join sections of the catheter shaft,

70. "The proximal end 32 of the distal shaft 23 extends over the distal end  
71. 30 of the main shaft section 22 and is attached thereto by a suitable bond such  
72. as a cyanoacrylate adhesive" (See Column 6 lines 28-30).

73. Ressemann ('291) fails to disclose the presence of a plurality of offset cuts on the bending section and fails to disclose a seal.

74. However, Schwartz ('520) does describe a bending section formed by a plurality of offset cuts (See Figure 17).

75. Furthermore, Schwartz ('520) proceeds to describe a biocompatible encasing or seal over the cut section (See 104 Figure 20).

76. It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the Ressemann ('291) proximal bending section of the catheter shaft by adding offset cuts to the section as taught by Schwartz in order to

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obtain a more flexible proximal catheter shaft section of the type disclosed by Ressemann ('291) and further to provide a seal over the offset cut section in order to produce a fluid sealed flexible catheter section of the type described by Schwartz ('520).

77. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to use an adhesive as disclosed by Ressemann ('291) in order to affix the seal.

78. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) in view of DeVries ('448).

79. Ressemann ('291) describes a catheter shaft including a proximal end and a distal end having secured thereto a balloon, and a luer fitting arranged at the proximal end of the catheter shaft, and the proximal end of the catheter shaft being provided with a bending section, (See Figure 1). Ressemann ('291) fails to disclose that the bending section is formed as a soft-annealed material section of the catheter shaft.

80. DeVries ('448) describes a "a metallic shaft, the distal end of which is annealed to a soft and flexible but shape retaining condition" (See Claim 2).

81. It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the Ressemann ('291) proximal bending section of the catheter shaft by a process of soft-annealing as taught by DeVries ('448) in order to form a flexible catheter shaft section as described by DeVries ('448).

82. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) and DeVries ('448) as applied to claim 9 above, and further in view of Sater ('480).

83. Ressemann ('291) describes a catheter shaft including a proximal end and a distal end having secured thereto a balloon, and a luer fitting arranged at the proximal end of the catheter shaft, and the proximal end of the catheter shaft being provided with a bending section, (See Figure 1). Ressemann ('291) fails to disclose that the bending section is formed as a soft-annealed material section of the catheter shaft nor does Ressemann ('291) describe a surrounding spiral spring element.

84. DeVries ('448) describes a "a metallic shaft, the distal end of which is annealed to a soft and flexible but shape retaining condition" (See Claim 2). DeVries fails to disclose a surrounding spiral spring element.

85. Sater ('480) describes a strain relief coil or spiral spring surrounding the catheter body (See Figure 1).

86. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the Ressemann ('291) proximal bending section of the catheter shaft by a process of soft-annealing as taught by DeVries ('448) in order to form a flexible catheter shaft section and to surround it with a spiral spring as taught by Sater ('480) in order to achieve a more flexible catheter body of the type disclosed by Sater ('480).

87. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) in view of Gillespie ('914).

88. Ressemann ('291) describes a catheter shaft including a proximal end and a distal end having secured thereto a balloon, and a luer fitting arranged at the proximal end of the catheter shaft, and the proximal end of the catheter shaft being provided with

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a bending section, (See Figure 1). Furthermore, Ressemann ('291) discloses a transition member of the fitting, consisting of plastic, which forms the bending section (See 60 Figure 2 and Column 9 lines 59-64). Ressemann ('291) does not disclose the presence of an undercut within the transition member, which is engaged be a complementary holding member of the proximal end of the catheter shaft.

89. Gillespie ('914) does describe an undercut within the transition member, which is engaged be a complementary holding member of the proximal end of the catheter shaft (See Figure 2).

90. It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the Ressemann ('291) catheter shaft and transition member by adding an undercut engagement feature as taught by Gillespie ('914) in order to attach the proximal end of the catheter shaft to the transition member.

91. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) in view of Magram ('254).

92. Ressemann ('291) describes a catheter shaft including a proximal end and a distal end having secured thereto a balloon, and a luer fitting arranged at the proximal end of the catheter shaft, and the proximal end of the catheter shaft being provided with a bending section, (See Figure 1). Ressemann ('291) fails to disclose that the bending section is comprised of a plurality of balls mounted on the proximal end of the catheter shaft.

93. Magram ('254) describes a bending section comprised of a plurality of balls (See Figure 3a).

94. It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the Ressemann ('291) catheter shaft and proximal bending section by adding a plurality of balls as taught by Magram ('254) in order to achieve a more flexible proximal catheter shaft section of the type disclosed by Magram ('254).

95. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ressemann ('291) in view of Sater ('480).

96. Ressemann ('291) describes a catheter shaft including a proximal end and a distal end having secured thereto a balloon, and a luer fitting arranged at the proximal end of the catheter shaft, and the proximal end of the catheter shaft being provided with a bending section, (See Figure 1). Ressemann fails to disclose that the bending section is designed as a flexible spiral spring, fastened to the proximal end of the catheter shaft and mounted on the fitting.

97. Sater ('480) describes a bending section of a catheter designed as a flexible spiral spring, which is mounted to the proximal end of the catheter shaft (See Figure 1).

98. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the Ressemann ('291) catheter shaft and proximal bending section mounted on the fitting by designing the bending section as a flexible spiral spring as taught by Sater ('480) in order to achieve a more flexible proximal catheter shaft of the type described by Sater ('480).



***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,741,429 to Donadio et al.

U.S. Pat. No. 6,387,075 to Stivland et al.

U.S. Pat. No. 6,387,076 to Landuyt.

U.S. Pat. No. 5,344,399 to DeVries

U.S. Pat. No. 5,630,806 to Inagakai et al.

CA 2085978 A1

EP 3907549A1

EP 0792655 A2

FR 1290933

WO 9218193 A1

WO 9616690 A1

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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